UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessments for the fungicide imazalil. Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health risks associated with the current use of imazalil. EPA is now publishing its reregistration eligibility and risk management decisions for the current uses of imazalil and its associated human health and environmental risks. The enclosed "Reregistration Eligibility Decision for Imazalil" contains the Agency's most current occupational and ecological risk assessments, and reregistration eligibility decision on the individual chemical imazalil, which was approved on September 30, 2003. EPA's dietary and aggregate risk assessment, and the tolerance reassessment are not included in the Reregistration Eligibility Decision (RED). These risk assessments and tolerance reassessment can be found in the Tolerance Reassessment Decision Document (TRED) dated July 12, 2002 (attached as Appendix C to this document).

A Notice of Availability for the imazalil RED is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket at (703) 305-5805. Electronic copies of the RED and TRED and all supporting documents are available on the Internet at the following address: http//:www.epa.gov/edockets.

This document and the process used to develop it are the result of a process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. Subsequently, the preliminary risk assessment for imazalil was made available to the public for comment on March 27, 2002 (67 FR 14710), and the revised risk assessment on June 25, 2003 (68 FR 37809). This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. In cooperation with the U.S. Department of Agriculture, the Agency also conducted a close-out conference call on September 29, 2003, with various stakeholders to discuss the risk management decisions and resultant changes to the imazalil labels.

Please note that the imazalil risk assessment and the attached RED document concern only this particular pesticide. FQPA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA did not perform a cumulative risk assessment as part of this reregistration review for imazalil, because it has not yet determined if there are any other chemical substances that have a mechanism of toxicity common with that of imazalil. For purposes of this reregistration decision, EPA has assumed that imazalil does not have a common mechanism of toxicity with other substances.

This document contains both generic and product-specific Data Call-Ins (DCIs) that outline further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, will be sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of required responses is due 90 days from receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

As part of the RED, the Agency has determined that imazalil will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the RED document. Sections IV and V of the RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency may have concerns about the risks posed by imazalil Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency’s action.

If you have questions on this document or the proposed label changes, please contact the Chemical Review Manager for imazalil, Cecelia Watson at (703) 305-4329. For questions about product reregistration and/or the product-specific DCI that accompanies this document, please contact Venus Eagle at (703) 308-8045.

Sincerely,

Betty Shackleford, Acting Director
Special Review and Reregistration Division

Enclosure

REREGISTRATION ELIGIBILITY DECISION

for

IMAZALIL

CHEMICAL LIST B

CASE NO. 2325

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IMAZALIL REREGISTRATION ELIGIBILITY DECISION TEAM

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Health Effects Risk Assessment

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GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWEL	Drinking Water Equivalent Level. The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EC_{50}	Effective Concentration for aquatic plants and invertebrates. The concentration of a chemical in water at which an effect is observed that is 50% of the maximum effect.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory. The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal,

	inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal. The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAFTA	North American Free Trade Agreement
NAWQA	(USGS) National Water Quality Assessment
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	(EPA) Office of Pesticide Programs
OPPTS	(EPA) Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	(USDA) Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Pesticide Root Zone Model and Exposure Analysis Modeling System, which is a Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval

RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. Concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) has completed its reregistration eligibility decision for the fungicide imazalil. The Agency has determined that imazalil products, labeled and used as specified in this Reregistration Eligibility Decision (RED) document, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency has determined that imazalil is eligible for reregistration under the conditions specified in this RED document.

This document presents the Agency's occupational and ecological risk assessments for imazalil. EPA's dietary and aggregate risk assessments, and tolerance reassessment for imazalil can be found in the Imazalil Tolerance Reassessment Decision Document (TRED) dated July 12, 2002 (attached as Appendix C to this document).

Imazalil was first registered in 1983. Since then, imazalil has continuously had one or more FIFRA Section 3 registrations for post-harvest use on citrus fruits against various fungi. Imazalil is also used as a fungicide for the treatment of barley and wheat seeds prior to planting, and as a fungicide to treat equipment and egg storage areas in chicken hatcheries.

Overall Risk Summary

The Agency's human health risk assessment for imazalil indicates some cancer and non-cancer risk concerns for occupational exposure. In the July 12, 2002, Tolerance Reassessment Decision Document (TRED), EPA concluded that there is a reasonable certainty of no harm to any population subgroup from aggregate exposure to imazalil from dietary exposure and all other non-occupational sources of imazalil exposure for which there is reliable information. There are no ecological risk concerns when imazalil is used as currently labeled.

The primary target organ for imazalil toxicity in animals is the liver. Imazalil is classified as "likely to be a carcinogen in humans," according to EPA's July 1999 Draft Guidelines for Carcinogen Assessment. Carcinogenicity studies in rodents indicate imazalil is carcinogenic to male Swiss albino mice and Wistar rats, based on a significant increase in liver adenomas and combined adenomas/carcinomas. In a rat study, there was also increased incidence of combined thyroid follicular cell adenomas/carcinomas. While the Agency has quantified the human cancer risk by a linear low-dose (Q_1^*) model, the registrant provided additional analysis and information intended to support the threshold approach for imazalil. This information is currently being reviewed by the Agency. In addition, the registrant plans to submit an additional study this year that they believe will provide sufficient evidence that imazalil is a threshold carcinogen. EPA will reconsider the appropriateness of the linear low dose (Q_1*) model depending on the results of the Agency's review of the new information, and if appropriate, amend this RED.

The results of the non-cancer short, intermediate, and long-term dermal and inhalation

risk assessments show that most occupational exposure scenarios are not a concern for the Agency, even with baseline attire (i.e., long pants, long sleeved shirts, no gloves). The exception is mixing/loading the liquid formulation of imazalil for use in citrus waxing equipment. However, with the addition of chemical resistant gloves, the risk for this scenario is also not a concern.

The results for occupational cancer risk assessment show that all 13 imazalil handler scenarios evaluated are below the Agency's level of concern provided that workers wear chemical resistant gloves. Most imazalil labels currently require the use of chemical resistant gloves.

The Agency has determined that there is potential post-application exposure to workers handling citrus fruits after foaming or waxing, to persons working in chicken hatcheries, and to persons handling treated seeds. EPA has concluded, under the conditions specified in this RED document, the post-application risks are all below the Agency's level of concern. However, at this time, there are no data available to adequately address the risk to handlers who handle used smoke canisters for the purpose of disposal.

Regulatory Decision

The Agency has concluded, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), that imazalil products, when labeled and used as specified in this document, will not cause unreasonable adverse effects on human health or the environment and, therefore, are eligible for reregistration.

Risk Mitigation

For the potential occupational cancer risks associated with use of imazalil over a lifetime, the use of chemical resistant gloves is necessary for the following scenarios:

- Mixing/loading liquid for on-farm seed treatment.
- Mixing/loading liquid for drencher application.
- Mixing/loading liquid for waxing equipment.
- Mixing/loading liquid for foaming equipment.
- Handling for commercial seed treatment.
- Mixing/loading and applying liquid with commercial seed treatment equipment.
- Mixing/loading/applying seed treatment for on-farm seed treatment.
- Handling used smoke canisters for disposal.

To further address occupational cancer risk concerns for imazalil used in chicken hatcheries:

- Smoke canisters containing imazalil for use in chicken hatcheries must have a label statement which requires all workers to immediately leave the treatment area after lighting the smoke canister.
- All workers must be prohibited by the label from reentering the treated area while smoke is still visible.

- Workers must be prohibited from reentering unventilated areas for 12 hours. For ventilated areas, workers may reenter after two hours provided at least one air exchange has occurred during that period (this statement applies to the smoke canister and EC formulations of imazalil).

To clarify that imazalil is not registered for use in chicken hatcheries when eggs and poultry are present, labels must state:

- This product may not be used when eggs or poultry are present.

EPA considered requiring chemical resistant gloves to further reduce imazalil post-application exposure to workers handling imazalil treated citrus. Several public comments on the imazalil risk assessments noted that the use of chemical resistant gloves (i.e., latex gloves) would be a problem for the industry. The fruit would be waxed by the time workers could be exposed to imazalil treated citrus fruit. Use of latex gloves would smudge the wax on the fruit. This is a cosmetic issue that hurts the marketability of the fruit. Second, the use of latex gloves would also be a heat and comfort burden to workers on the packing line. In light of these concerns, the Agency reviewed the assumptions used in the risk assessment for this post-application exposure scenario and concluded that the assumptions regarding dermal contact were very conservative. Therefore, based on the conservative nature of the assessment, the Agency believes the risk to workers for this scenario are below the level of concern even without chemical resistant gloves. To confirm this conclusion and refine our risk estimates, the Agency will require data on the availability of imazalil which is either part of a wax matrix, or encapsulated with wax.

Jenssen Pharmaceutica, one of the registrants of the liquid formulations of imazalil that can be used to treat post-harvest citrus, has indicated, in their comments to the revised imazalil risk assessment, that they intend to voluntarily cancel the use of imazalil for foaming equipment. There are two other registrants that continue to support this use. However, based on comments from the citrus industry, foaming is not commonly used and they support the voluntary cancellation of this application method.

In order to assure that no workers are not exposed when imazalil is applied to citrus in truck-beds, the following label statements must be added:

- Stay outside the treatment area until citrus is treated and drained.
- The windows and doors of the transport vehicle must be closed prior to treatment.

EPA believes these label requirements are consistent with current industry practice; however, EPA would like to ensure these practices are followed.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all existing tolerances. EPA's dietary and aggregate risk assessments, and tolerance reassessment for imazalil can be found in the Tolerance Reassessment Decision Document (TRED) dated July 12, 2002 (attached as Appendix C to this document). You may also view this document in EPA's electronic public docket system, http://www.epa.gov/edocket/. Once in the system, select "search," then key in the docket ID number, OPP-2002-0333. The Agency is also in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Imazalil will be reevaluated at that time and additional testing may be required.

This document presents the Agency's most current occupational and ecological risk assessments; and completes the reregistration process for imazalil. This document consists of six sections. Section I contains the regulatory authority and framework for reregistration. Section II provides a regulatory history and profile of the use and usage of the chemical. Section III gives an overview of the human health and environmental effects risk assessments. Section IV presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions. Section V identifies label changes necessary to implement the risk mitigation measures. Finally, among the Appendices in Section VI is a description of the revised use patterns, generic and product-specific DCI, the July 12, 2002, Tolerance Reassessment Decision, and other reference information. The risk assessments and supporting documents are not included in this document, but are available in the public docket and the electronic docket at http://www.epa.gov/edocket/.

II. Chemical Overview

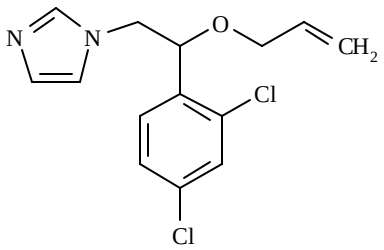
A. Regulatory History

Imazalil is a List B reregistration pesticide. Imazalil was first registered by Janssen Pharmaceutica (FIFRA Section 3) in 1983. Since then, imazalil has continuously had one or more FIFRA Section 3 registrations for postharvest use on citrus fruits against various fungi. In 1984, the Agency first registered imazalil for use in seed treatment, and in 1990 for use in chicken hatcheries. There are 15 registered products including two technical grade products (Magnate technical 98.50-98.94% active ingredient), one impregnated material (14.9% a.i.), 4 liquids (up to 31% a.i.), seven emulsifiable concentrates (up to 68.25% a.i.), and a flowable concentrate (10 % a.i.). Impregnated material is used in smoke generators.

EPA completed the tolerance reassessment for imazalil on July 12, 2002. The Tolerance Reassessment Decision Document (TRED) is attached as Appendix C to this document. In the July 12, 2002 TRED, EPA concluded that there is a reasonable certainty of no harm to any population subgroup from aggregate exposure to imazalil from dietary (food and water) exposure and all other non-occupational sources for which there is reliable information.

B. Chemical Identification

Imazalil:



- **Common Name:** Imazalil
- **Chemical Name:** 1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*-imidazole
- **Case number:** 2325
- **CAS registry number:** 73790-28-0
- **OPP chemical code:** 111901
- **Empirical formula:** $C_{14}\ H_{14}Cl_2\ N_2\ 0$
- **Molecular weight:** 297.17

- **Trade and other names:** Fecundal ®; Fungaflor ®**,** Magnate®

- **Basic manufacturer:** Janssen Pharmaceutica, N.V. and Makhteshim-Agan of North America

Imazalil is a yellow or brown crystalline solid with a melting point of 50° C, density of 1.348 x 103 kg/m3, octanol/water partition coefficient (log Pow) of 3.82, and vapor pressure of 3.6 x 10-4 Pa at 25° C. Imazalil is slightly soluble in water (293 ppm at 20° C), and is very soluble in methanol, ethanol, 2-propanol, dimethylbenzene, acetonitrile, N, N-dimethylformamide, tetrahydrofuran, 1-methyl-2-pyrrolidinone, 1,2-ethanediol, 1,2-propanediol, and glacial acetic acid (>500 g/L at 25° C).

C. Use Profile

The following information is based on the currently registered uses of imazalil:

Type of Pesticide: Systemic fungicide**.**

Summary of Use Sites:

Food: Post harvest treatment of bananas (import tolerance only) and citrus fruits, and treatment of barley and wheat seeds prior to planting.

Residential: None.

Public Health: None.

Other Non-food: Fungicide for chicken hatcheries.

Target Pests: Plant pathogenic fungal organisms consisting of:

barley leaf rust, blue mold fruit rot (Penicillium italicum), common root rot of wheat, Diplodia rot (Diplodia natalensis), fruit rot (Alternaria), green mold fruit rot (Penicillium digitatum), melanose (Diaporthe), net blotch (Pyrenophora), Penicillium mold/rot, root rot (Fusarium), root rot (Helminthosporium), seedling blight/rot (Fusarium), seedling blight/rot (Helminthosporium), seedling blight/rot (Penicillium), septoria glume blotch (S. nodurum), stem-end rot (Diplodia), stem-end rot (Phomopsis), stripe (Helminthosporium);

Poultry pathogens consisting of: aspergillosis (Aspergillus fumigatus)

Formulation Types Registered: Formulated as impregnated material for use in smoke generators (14.9% active ingredient(a.i.)), liquid (up to 31% a.i.),

emulsifiable concentrate (up to 68.25% a.i.), and flowable concentrate (10% a.i.).

Method and Rates of Application:

Equipment - Seed treatment equipment, truck-bed drenchers, fruit waxing and foaming equipment, high pressure handwand sprayers, and smoke canisters.
Method and Rate
Seed treatment equipment: up to 0.01 lb a.i./100 lbs of seed.
Drencher: 0.6255 lb a.i./100 gallons
Waxing equipment: 1.665 lb a.i./100 gallons.
Foaming equipment: 1.665 lb a.i./100 gallons.
Handwand sprayers: 0.00032 lb a.i./1000 ft^3.
Smoke generator: 0.022 lb a.i.e/1,000 ft^3

Timing - Pre-planting for seeds; post harvest for citrus; for use in chicken hatcheries prior to introduction of eggs.

Use Classification: Unclassified

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of imazalil, based on available pesticide usage information for 1994-95. A full listing of all uses of imazalil, with the corresponding use and usage data for each site, has been completed and is in the November 5, 2001, "Quantitative Usage Analysis" document (Jihad Alsadek, 2001), which is available in the public docket and internet. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 6,000 lbs a.i. of imazalil are used annually, according to Agency and registrant estimates.

Table 1. *Imazalil* Estimated Usage for Representative Sites*

Crop	# Applications	% of Crop Treated	Lbs. of AI Used
Oranges	1 Post-harvest	18-22	1,900-2,100
Tangerines	1 Post-harvest	-	250-325
Grapefruit	1 Post-harvest	43-47	1,450-1,650
Lemons	1 Non Storage 1 Pre-Storage 1 Post-harvest	- - -	900-1100 780-900 75-85
Limes	1 Post-harvest	-	18-22
Bananas	1 Post-harvest	-	12-16
Barley	1 Seed-treatment	-	-
Wheat	1 Seed-treatment	-	-
Total			5,385-6,198

* Based on EPA Data, 1994-95, and crop profiles for barley and hard red spring and durum wheat in North Dakota, December, 2000.

III. Summary of Imazalil Risk Assessment

The following is a summary of EPA's revised occupational and ecological risk findings and conclusions for the pesticide imazalil, as fully presented in the documents, "Imazalil: HED Risk assessment for Reregistration Eligibility Decision (RED) Document" dated February 7, 2002 (and addenda thereto), and "Environmental Risk Assessment for the Reregistration of Imazalil," dated April 18, 2001. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to enhance understanding of the conclusions reached in the assessments.

A. Human Health Risk Assessment

EPA issued its preliminary human health risk assessment for imazalil on February 7, 2002. After review of public comments, the Agency has determined that these risk assessments do not need to be updated for this RED. Please see the July 12, 2002 TRED to see the specifics of the Agency's tolerance reassessment decision for acute and chronic dietary, and drinking water risk assessment (Appendix C). In the July 12, 2002 TRED document, EPA determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to imazalil when considering dietary (food and water) exposure and all other non-occupational sources of pesticide exposure for which there is reliable information.

1. Residential Risk

There are no registered residential uses of imazalil and thus residential exposure is not expected.

2. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of imazalil include: individual farmers or growers who mix, load, and/or apply pesticides, and professional or custom agricultural applicators. Non-cancer risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). For imazalil, MOEs greater than 100 do not exceed the Agency's level of concern. Occupational cancer risks greater than 1×10^{-4} (one in ten thousand) exceeds the Agency's level of concern. EPA closely examines occupational cancer risks in the 1×10^{-4} and 1×10^{-6} range and seeks cost effective ways to reduce the risk to the greatest extent feasible, preferably 10^{-6} or less.

a. Toxicity

The toxicity of imazalil is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for imazalil. The primary target organ for imazalil toxicity in animals is the liver. The toxicological endpoints, and other factors used in the occupational risk assessments for imazalil are listed below and in Table 2.

- For estimating intermediate- and long-term dermal risks, EPA used oral animal studies in the absence of appropriate dermal toxicity studies. The dermal absorption factor is 41%, based upon the maximum blood concentration observed in a rat dermal absorption study. This factor was used for converting dermal exposures to equivalent oral doses.

- For estimating short-, intermediate- and long-term inhalation risks, EPA used oral animal studies in the absence of appropriate inhalation toxicity studies. EPA assumes 100% of the inhaled imazalil dose is absorbed by the body.

- Imazalil is classified as "likely to be a carcinogen in humans," according to EPA's July 1999 Draft Guidelines for Carcinogen Assessment. Carcinogenicity studies in rodents indicate imazalil is carcinogenic to male Swiss albino mice and Wistar rats, based on a significant increase in liver adenomas and combined adenomas/carcinomas. In rats there was also increased incidence of combined thyroid follicular cell adenomas/carcinomas.

- Based on current science policy and absent information demonstrating a mode of action in test animals, EPA quantified the human cancer risk by a linear low-dose (Q_1^*) extrapolation. The most potent unit risk, $Q_1^*(mg/kg/day)^{-1}$ for imazalil based on male mouse liver adenoma and/or carcinoma combined tumor rates, is 6.1×10^{-2} $(mg/kg/day)^{-1}$

in human equivalents. Since the July 12, 2002, TRED, the registrant conducted a cell proliferation study designed to determine the mode of action for carcinogenicity. This information was intended to support the use of a threshold cancer model for imazalil. The Agency reviewed the study and concluded the case for a threshold cancer model for imazalil was not supported by the submitted data. Therefore, EPA concluded the Q_1* model is currently the most appropriate model to characterize the cancer risk for imazalil. During the Phase 5 public comment period for imazalil, the registrant provided additional analysis and information intended to support the threshold approach for imazalil. This information is currently being reviewed by the Agency. The registrant also indicated that in December 2003, they will submit the results of a 5-day study which they believe, when considered with all available data and information on the carcinogenic mechanism for imazalil, will provide sufficient evidence that imazalil is a threshold carcinogen. The data from the 5-day study will further characterize the early mitogenic burst seen in nongenotoxic promoters such as phenobarbital. EPA will evaluate the appropriateness of the linear low dose (Q_1*) model depending on the results of the review of the information submitted, and if appropriate, amend this RED.

Table 2: Endpoints for Assessing Occupational Risks for Imazalil

EXPOSURE SCENARIO	DOSE (mg/kg/day)	EFFECT	STUDY (MRID)	Target MOE
Dermal Absorption	41% based on a dermal absorption study in male rats			
Short-Term (Dermal)	Dermal NOAEL=160 LOAEL=250	Skin effects and swollen livers	21 Day Dermal - Rabbit (42085201)	100
Intermediate-Term (Dermal)	Oral NOAEL=15.8 LOAEL=32	Severe liver effects	Subchronic Study - Rats (43965704)	100
Long-Term (Dermal) (Non-cancer)	Oral NOAEL=2.5 LOAEL=20	Systemic toxicity: vomiting, soft stools, ↓body weight gain, ↑liver weight, ↑alkaline phosphatase	Chronic Toxicity-Dogs (41328802)	100
Cancer	$Q_1^* = 6.11 \times 10^{-2}$	Hepatocytic neoplasm	Carcinogenicity Study Mice (42972001)	NA
Acute Inhalation	Not required: acute inhalation is category IV. Acute exposure not likely.			
Short-term Inhalation	Oral NOAEL = 5 LOAEL=10	Increased resorption and decreased fetuses	Developmental-Rabbit Study (42593601)	100
Inhalation (Intermediate and long term)	Oral NOAEL = 2.5 LOAEL 20	Systemic toxicity: vomiting, soft stools, ↓body weight gain, ↑liver weight, ↑alkaline phosphates	Chronic Toxicity-Dogs (41328802)	100

The acute toxicity of imazalil is summarized in Table 3 below:

Table 3: Acute Toxicity Profile for Occupational Exposure for Imazalil

Study Type	MRID #	Results	Toxicity Category
Acute Oral: Rats	000315964 4107212	LD_{50} = 343 mg/kg LD_{50} = 480-679 mg/kg	II II
Acute Dermal: Rabbits	41606104 44107213	LD_{50} = >2000 mg/kg LD_{50} = >2000 mg/kg	III III
Acute Inhalation: Rats	44107214	LC_{50} = 2.43 mg/L	IV
Primary Eye Irritation	41606105	Irritating	I
Primary Skin Irritation	44107216	Mild-irritation	IV
Dermal Sensitization	41718701 40271701	Non-sensitizer	IV

b. Exposure

The Agency has determined that there are potential exposures to mixers, loaders, applicators, or other handlers resulting from application of imazalil for seed treatment, post harvest application to citrus, and chicken hatcheries. Based on the use patterns and potential exposures described above, thirteen major handler exposure scenarios are identified to represent the extent of imazalil uses. Exposure scenarios include: (1) private farmers mixing/loading liquid formulation for on- farm seed treatment, (2) mixing/loading liquid formulation for drencher application of citrus in trucks, (3) mixing/loading liquid formulation for citrus waxing equipment, (4) mixing/loading the liquid formulation for citrus foaming equipment, (5) mixing/ loading liquid formulation for high pressure handwand applications in chicken hatcheries, (6) applying liquid formulation to post-harvest citrus in a truck using a drencher, (7) applying liquid to post harvest citrus using foaming equipment, (8) applying liquid formulation to post harvest citrus using waxing equipment, (9) applying liquid formulation with a high pressure handwand sprayer in chicken hatcheries, (10) commercial application for seed-treatment equipment after harvest prior to storage, (11) applying/lighting smoke canisters in chicken hatcheries, (12) mixing/loading and applying liquid with commercial seed-treatment equipment, and (13) private farmers mixing/loading and applying for on-farm seed treatment.

Seed treatment exposure data were used by the Agency to assess the potential handler exposure to imazalil. The Agency also used data from the Pesticide Handlers Exposure Database (PHED) to supplement the chemical-specific data and to assess the exposure scenarios for which no exposure data were provided by the registrant; however, there are a few scenarios that could not be assessed because of lack of data.

Occupational handler exposure assessments are conducted by the Agency using different

levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to reduce risks as needed (i.e., going from minimal to maximum levels of protection). The lowest level of protection is baseline, or standard work attire (long sleeved shirt, long pants, shoes, socks). If necessary (i.e., MOEs are less than 100 or cancer risks are greater than 1 $x10^{-6}$), increasing levels of personal protective equipment (PPE) are applied. If MOEs are still less than 100 or cancer risk is still greater than $1x10^{-6}$, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or EC's taken from a current label.

The levels of protection that formed the basis for calculation of exposure from imazalil scenarios include:

Baseline: Long-sleeved shirt and long pants, shoes and socks (no gloves), and
PPE: Baseline with the addition of chemical resistant gloves.

Dermal and inhalation MOEs were calculated for handlers for short-term duration (up to 30 days), intermediate-term (up to 180 days) and long-term (over 180 days). Lifetime cancer risks were also calculated for the various handler scenarios.

c. Occupational Risk Summary

In the case of imazalil, dermal and inhalation risks are assessed separately since the toxicological endpoints for these exposures are not based on the same effects. Exposures to imazalil are expected to be short, intermediate and long-term by dermal and/or inhalation routes of exposure. Life-time cancer risk is also calculated for the various scenarios.

(1) Occupational Handler Summary (Non-Cancer)

Table 4 presents the risk at baseline and with PPE for each exposure scenario. The results of the non-cancer short, intermediate, and long-term dermal and inhalation risk assessments show that all scenarios for which there were data available have MOEs greater than or equal to 100 at baseline attire (i.e., long pants, long sleeved shirt, no gloves), except for mixing/loading liquid formulation for waxing equipment (scenario 3 on Table 4). However, the risk from mixing and loading liquid formulation for waxing equipment is no longer a concern with the addition of chemical resistant gloves.

There were insufficient data for the Agency to quantify risks for the following five scenarios:

- Mix/load liquid for foaming equipment (scenario 4)
- Application of liquid with drencher (scenario 6)
- Application of liquid with foaming equipment (scenario 7)
- Application of liquid with waxing equipment (scenario 8)
- Application using smoke canister for chicken hatchery (scenario 11)

Although the risks for these scenarios have not been quantified, the Agency does not believe there are risks of concern associated with these scenarios. EPA does not expect the risk

for mixing and loading liquid for foaming equipment to be substantially different from mixing and loading liquid for waxing, which has risks below EPA's level of concern with the addition of gloves. For the drenching, foaming and waxing, application scenarios, occupational exposure is unlikely because these operations are mechanically and remotely performed (i.e., the applicators are not present in the treatment area when imazalil is applied).

Finally, the Agency did not have data to do a quantitative risk assessment for handlers applying and lighting smoke generators in chicken hatcheries (scenario 11). However, the Agency did a very conservative assessment in order to bound the risk to handlers using smoke generators containing imazalil. In this assessment, the air concentration was calculated at the maximum application rate (i.e., the assessment assumed the entire contents of the can were immediately made available for exposure). It was also assumed that the handlers were exposed to imazalil from the smoke generator for a period of one minute. This assumption is also very conservative because we understand that it is established industry practice to immediately leave the treatment area once the smoke canister is lit. Even with these very conservative assumptions, MOEs were 50 for short-term and 30 for intermediate-term (see Table 4a). Given the very conservative assumptions used for the exposure estimates, EPA expects the actual risk to applicators using smoke canisters to be below our level of concern.

(2) Occupational Risk (Cancer)

Cancer risk assessments for handlers were completed by EPA using a baseline exposure scenario and, as needed, increasing levels of risk mitigation (PPE) to achieve cancer risks that are below the Agency's level of concern. Table 4 presents cancer risk calculations at baseline and with PPE for each exposure scenario. The calculations of daily dermal and inhalation exposure to imazalil by handlers were used to calculate the daily dose, and hence the risks, to those handlers.

The following assumptions and factors were used in order to complete this cancer risk assessment:

- The average body weight of 70 kg is used, representing a typical adult.
- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.
- Lifetime is assumed to be 70 years.
- The Q_1^* used in the cancer assessment was 6.11×10^{-2} (mg/kg/day)$^{-1}$.
- Exposure frequencies used in the calculations are: 250 days for chicken hatcheries (based on Agency analysis), 15 days for commercial seed treatment, 10 days on-farm seed treatment, and 100 days for commercial citrus applicator.

The results of the cancer risk assessment (see Table 4) show that of the thirteen handler scenarios evaluated with PPE, one scenario was 1.50×10^{-4} to 2.25×10^{-4} (Scenario 13: mixing, loading, and applying imazalil for on-farm seed treatment), three scenarios were in the 10^{-5} range (Scenarios 3, 12 and 13: mixing/loading for waxing equipment; and mixing, loading, applying for both on-farm and commercial seed treatment), and five scenarios where in the 10^{-6} to 10^{-7} range (Scenarios 1, 2, 9 and 10). EPA did not do a quantitative assessment for the remaining

scenarios because of lack of data. Most current imazalil labels prescribe the following PPE for all handlers: long sleeved shirt and long pants, gloves, shoes, socks, and protective eye-wear.

The risk of 1.50×10^{-4} to 2.25×10^{-4} for scenario 13 is a screening level estimation of risk. The dermal exposure for this scenario was derived from a literature study in which a dust formulation was used to derive dermal exposure estimates (Fenske et.al.). For loading seed into a hopper box for planting, dust formulations, which can linger in the air, have a significantly higher potential for exposure than the imazalil emulsifiable concentrates formulation actually used for on-farm seed treatment. Therefore, the Agency believes that this screening level risk estimate significantly over estimates the risk, and that the actual risk is well below that requiring further action.

The Agency also did an assessment to bound the risks for handlers lighting and using smoke generators (scenario 11). Using the very conservative assumptions described in the previous section on non-cancer occupational risk (see Section III.2.c.1, "Occupational Handler Summary (Non-Cancer)"), the Agency estimated a cancer risk of 1.7×10^{-3} (see Table 4a). As stated in the previous section, given the very conservative assumptions used in this exercise, EPA expects the actual risk to applicators lighting and using smoke canisters to be below our level of concern.

Table 4: Summary of Exposure Variables, MOEs and Cancer for uses of Imazalil

Exposure Scenario (Scenario #)	Range of Application Rates (lb ai/A)	Amount Handled per Day	Short-Term Dermal MOEs		Intermediate-Term Dermal MOEs		Long-term Dermal MOEs		Short-Term Inhalation MOEs		Intermediate, Long-Term Inhalation MOEs		Cancer	
			Base line	PPE	Base line	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE
Mixer/Loader														
Mixing/loading liquid formulation for on farm seed treatment (1)	0.003906 lb/100 lb	12,000	8.25e+03	NA	NA	NA	NA	NA	5.33e+05	NA	NA	NA	1.63e-05 2.44e-05	1.37e-07 2.05e-07
	0.01 lb/100 lbs		3.20e+03	NA	NA	NA	NA	NA	2.08e+05	NA	NA	NA	4.16e-05 6.24e-05	3.50e-07 5.25e-07
Mixing/loading liquid (EC) for Drencher application (2)	0.6255 lb ai/100 gallons	1,200 gallons	NA	NA	1.24e+02	NA	NA	NA	NA	NA	1.94e+04	NA	1.07e-03	9.55e-06
Mixing/loading liquid (EC) for a waxing equipment (3)	1.665 lb ai/100 gallons	1,600 gallons	NA	NA	3.48e+01	4.52e+03	NA	NA	NA	NA	5.46e+03	NA	3.80e-03	3.40e-05
Mixing/loading Liquid (EC) for a foaming equipment (4)	1.665 lb ai/100 gallons	No Data	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Mixing/loading liquid formulation for high pressure hand application (5)	0.00032 lb ai/1000 ft^3	4320ft^3	NA	NA	NA	NA	1.06e+05	NA	NA	NA	1.05e+07	NA	4.92e-07	NA
		37800 ft^3	NA	NA	NA	NA	1.22e+04	NA	NA	NA	1.21e+07	NA	4.30e-06	NA
Applicator														
Applying liquid formulation with a drencher (6)	0.6255 lb ai/100 gallons	1,200 gallons	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Applying liquid formulation for a foaming equipment (7)	1.665 lb ai/100 gallons	1,600 gallons	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Applying liquid formulation for a waxing equipment (8)	1.665 lb ai/100 gallons	No Data	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Applying liquid formulation with a high pressure handwand sprayer (9)	0.00032 lb ai/1000 ft^3	4320 ft^3	NA	NA	NA	NA	1.72+05	NA	NA	NA	1.61e+05	NA	3.36e-07	NA
		37800 ft^3	NA	NA	NA	NA	1.95e+04	NA	NA	NA	1.83e+04	NA	2.95e-06	NA
Handler for commercial seed treatment (10)	0.00671 lb ai/100 lbs Sudangrass	132,000	8.43e+04	NA	NA	NA	NA	NA	1.88e+05	NA	NA	NA	2.42e-06	3.83-07
		718,000	1.55e+04	NA	NA	NA	NA	NA	3.46e+04	NA	NA	NA	1.31e-05	2.08e-06
	Min 0.00396 lb ai/100lb wheat and barley	132,000	1.45e+05	NA	NA	NA	NA	NA	3.23e+05	NA	NA	NA	1.35e-06	2.23e-07
		718,000	2.66e+04	NA	NA	NA	NA	NA	5.94e+04	NA	NA	NA	7.66e-06	1.21e-06
	Max 0.01lb ai/100 lbs wheat and barley	132,000	5.66e+04	NA	NA	NA	NA	NA	1.26e+05	NA	NA	NA	3.60e-06	5.71e-07
		718,000	1.04e+05	NA	NA	NA	NA	NA	2.32e+04	NA	NA	NA	2.20e-06	3.10e-06

Table 4: Summary of Exposure Variables, MOEs and Cancer for uses of Imazalil

Exposure Scenario (Scenario #)	Range of Application Rates (lb ai/A)	Amount Handled per Day	Short-Term Dermal MOEs		Intermediate-Term Dermal MOEs		Long-term Dermal MOEs		Short-Term Inhalation MOEs		Intermediate, Long-Term Inhalation MOEs		Cancer	
			Base line	PPE	Base line	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE
Apply/light smoke canisters (11)	0.022 lb ai/1000 ft^3	No Data	NA	NA	NA	NA	No Data	No Data	NA	NA	No Data	No Data	No Data	No Data
Mixer/ Loader/Applicator														
Mixing/loading and applying liquid with commercial seed-treatment equipment (12)	0.00671 lb ai/100 lbs Sudangrass	132,000	3.51e+03	NA	NA	NA	NA	NA	2.42e+04	NA	NA	NA	5.74e-05	1.03e-05
		718,000	6.46e+02	NA	NA	NA	NA	NA	4.45e+03	NA	NA	NA	3.14e-04	5.58e-05
	Min 0.00396 lb ai/100lb wheat and barley	132,000	6.03e+03	NA	NA	NA	NA	NA	4.15e+04	NA	NA	NA	3.35e-05	5.98e-05
		718,000	1.11e+03	NA	NA	NA	NA	NA	7.63e+03	NA	NA	NA	1.82e-04	3.25e-05
	Max 0.01lb ai/100 lbs wheat and barley	132,000	2.36e+03	NA	NA	NA	NA	NA	1.62e+04	NA	NA	NA	8.56e-05	1.53e-05
		718,000	4.33e+02	NA	NA	NA	NA	NA	2.98e+03	NA	NA	NA	4.66e-04	8.32e-05
Mixing/loading/applying (EC) for on- farm seed treatment (13)	0.003906 lb/100 lb	12,000	See PPE	2.30e+03	NA	NA	NA	NA	See PPE	2.65e+05	NA	NA	See PPE	5.84e-05* 8.75e-05**
	0.01 lb/100 lbs		See PPE	8.96e+02	NA	NA	NA	NA	See PPE	1.04e+05	NA	NA	See PPE	1.50e-04* 2.25e-04**

***** Assumed 10-days exposure for private applicator

** Assumed 15-days exposure for commercial applicator.

Table 4a: Occupational Handler Short, Intermediate and Long-term inhalation Risk from smoke generator containing Imazalil (Screening Level Assessment)

Scenario[a]	PF	Short-term MOEs[e]	Intermediate, Long-term MOEs[f]	LADD[g]	Cancer[h]
Smoke generator (baseline)	1 (no respirator)	50	30	2.80e-02	1.7e-03

[a] Baseline represents the use of smoke generator without a respirator.

[c] Short-term inhalation dose (mg/kg/day) = airborne concentration of imazalil *inhalation rate (16.6 l/min)/body weight (60kg)

[d] Intermediate-long-term inhalation dose (mg/kg/day) = airborne concentration of imazalil *inhalation rate (16.6 l/min)/body weight (70kg)

[e] Short-term Inhalation MOE = NOAEL (5 mg/kg/day)/ Short-term Daily Inhalation Dose (mg/kg/day).

[f] Intermediate-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/ Intermediate-term Daily Inhalation Dose (mg/kg/day).

[g] LADD (mg/kg/day) = Daily Dose (mg/kg/day) * (Number of days exposure per year (250)) /365 days per year) * 35 years worked/70 year lifetime.

[h] Cancer Risk = LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).

(3) Post-Application Occupational Risk

EPA has determined that there is potential exposure to workers handling citrus fruits after waxing or foaming, to persons working in chicken hatchery facilities, and to persons handling treated seeds.

Post-Application Risk to Citrus Packing Workers

For citrus, the main post-application activities are sorting/culling or packing of products following imazalil treatment. The Agency has no data specifically addressing the exposure from those activities. Exposure estimates for citrus in the risk assessment were derived from residue chemistry data, surface area calculations, and a reentry study for citrus found in the scientific literature.

For non-cancer effects, risk from handling citrus was not of concern for intermediate term effects at baseline protection of (long pants, long sleeved shirt, no gloves). The MOE for this exposure scenario is 120 (See Table 5 below). Short-term MOEs were not calculated since this post application exposure is expected to exceed 30-days.

For cancer effects, the estimated lifetime cancer risk for citrus workers exposed to imazalil post- treatment was estimated to be 6.68×10^{-4} under the baseline exposure scenario. With the addition of protective gloves, the risk becomes 6.68×10^{-5} (See Table 5).

Table 5: Imazalil Intermediate-Term and Cancer Occupational Post-Application Assessment for Citrus (Waxing and Foaming)

Scenario[a]	Dermal Dose[b] (mg/kg/day)	Intermediate -term MOEs[c]	LADD[d]	Cancer[e]
Baseline	0.133	120	1.09e-02	6.68e-04
PPE	0.0133	NA	1.09e-03	6.68e-05

[a] Baseline represents long pants, long sleeved shirt and no gloves
PPE represents long pants, long sleeved shirt and gloves

[b] Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg) x dermal absorption factor (41%) .

[c] Intermediate-term Dermal MOE = NOAEL (15.8 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

[d] Baseline LADD (mg/kg/day) = Baseline Daily Dose (mg/kg/day) * (Number of days exposure per year (60)) /365 days per year) * 35 years worked/70 year lifetime.
PPE LADD (mg/kg/day) = PPE Daily Dose (mg/kg/day) * (Number of days exposure per year (60)) /365 days per year) * 35 years worked/70 year lifetime.

[e] Baseline Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).
PPE Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).
Dermal exposure (µg/kg/day) =1500 cm^2/hr x 1.9 µg/cm^2 x 8 hrs/day ÷ 70 kg (bw) x 0.41 (dermal absorption factor)
Dermal exposure (µg/kg/day) =133 µg/kg/day = 0.133 mg/kg/day

The exposure estimate for workers handling citrus fruits after waxing or foaming is considered to be very conservative. First, it was assumed that all of the imazalil on the treated surface would be transferred to the skin. However, based on Brouwer et al. (1999), the efficiency of transfer would be less than 2% of the contamination on a surface. This is a 50-fold reduction in the exposure from what was assumed in the risk assessment, which would reduce the risk by 50-fold as well. Second, imazalil is usually encapsulated in a wax matrix and

substantial transfer to the skin is unlikely. Finally, the transfer coefficients for the hands were obtained from a field study in which dermal contact with contaminated foliage was extensive; a conveyor belt treatment line as used for citrus would be unlikely to have such a high degree of contact (probably restricted to fingertips only). Therefore, EPA has concluded that the cancer risk to citrus packing workers is below the level which warrants a requirement for chemical resistant gloves.

Post-Application Risk to Chicken Hatchery Workers

Frequent disinfection of equipment and air which comes in contact with egg shells is required to prevent aspergillus molds in chicken hatcheries. Imazalil is only registered to be used on hatchery equipment when the eggs and poultry are not present. Before the eggs are transferred, the shelves and inside parameters of the setters or hatchers are treated with imazalil using handheld equipment (EC formulation) or a smoke generator. In the case of smoke generators, workers are prohibited by the label from reentering the treated area if smoke is still visible. Further, the current label states that workers should not reenter unventilated areas for 12 hours. For ventilated areas, workers may reenter after 30 minutes, and at least 1 to 2 air exchanges. For the liquid formulation of imazalil (EC), the label requires that workers wait at least two hours before reentering the treated site.

Given the nature of the activities at egg handling facilities, EPA believes that there is minimal dermal or inhalation exposure to imazalil in chicken hatcheries following imazalil applications provided there is adequate ventilation, or that sufficient time has elapsed after treatment, therefore, no post-application inhalation or dermal risk assessment was performed for reentry following smoke generator or spraying applications in chicken hatcheries (hatcher, setter and storage rooms). At this time, there are no data available to adequately address the return of handlers to hatchers or setters for the purpose of disposing of the used smoke canister.

Post-Application Risk to Workers From Imazalil-Treated Seed

There may be post-application exposure to workers handling and planting imazalil treated seeds. As there were no study data available on exposure to imazalil residues on treated seed, a conservative screening level assessment was performed using the unit exposure for handling granular formulations found in PHED. The screening assessment did show a cancer risk of concern (1.3×10^{-5} to 1.46×10^{-5}) as shown on Table 6. However, EPA believes that this assessment overestimates the risk to workers from post-application exposure to imazalil treated seeds for the following reasons. First, the PHED data were taken from studies on granular formulations of pesticides. Since these formulations are designed to release the active ingredient into the environment, the exposure estimates from the PHED studies will significantly overestimate exposure from treated seeds, where the active ingredient is tightly bound to the seed surface to protect the seeds. Second, the risk was calculated using maximum application rate and pounds treated and planted per day. The Agency would normally use typical application rates and average pounds treated/planted per day for a refined cancer assessment. Finally, since this assessment was completed, the Agency has developed a revised Seed Treatment Standard

Operating Procedure (SOP #14, dated May 2003), which relies on study data to calculate a unit exposure to treated seeds. If this risk assessment were revised consistent with that SOP, the unit exposure for planting the treated seed would be higher. However, the Agency would assume a maximum of 24,000 pounds of imazalil treated seed would be planted in a day rather than the 718,000 pounds assumed in the current assessment (a maximum of 200 acres would be planted, requiring 120 lbs of treated seed per acre). The result would be a risk of 1.08×10^{-5} for planting treated seeds. This would also be considered a conservative assessment because it assumes maximum application rate and pounds treated per day, as well as planting the maximum number of acres for a 35 year period. Therefore, this post-application scenario is below the Agency's level of concern.

The Agency did not conduct a quantitative assessment to calculate the post-application risk to workers exposed to imazalil-treated seed which has been planted. The Agency believes that there is a low potential for re-entry exposure for this scenario since the seeds are below the surface of the ground and therefore not available for worker exposure.

Table 6: Imazalil short-term, Intermediate-term and Q* Occupational post Application Assessment for Seed Treatment

Exposure Scenario	Baseline Dermal				Baseline Inhalation					Baseline Cancer	
	Short-term Daily Dose (mg/kg/day)[a]	Int-term Daily Dose (mg/kg/day)[b]	Short-term MOEs[c]	Int.-term MOEs[d]	Short-term Daily Dose (mg/kg/day)[e]	Intermediate-Term Daily Dose (mg/kg/day)[f]	Short-term MOEs[g]	Int-term MOEs[h]	Total Dose (mg/kg/day)[i]	LADD[j]	Cancer[k]
Mixer/Loader Exposure											
Mixing loading treated seed	8.62e-03	4.12e-03	1.86e+04	3.83e+03	2.30e-03	1.74e-03	2.46e+03	1.43e+03	1.02e-02	2.13e-04	1.30e-05
Applicator exposure											
Applying treated seed	1.02e-02	4.86e-03	1.54e+04	3.25e+03	1.44e-03	1.23e-03	3.48e+03	2.03e+03	1.16e-02	2.39e-04	1.46e-05

[a] Short-termDaily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).
[b] Intermediate-termDaily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg)*0.41.
[c] Short-term Dermal MOE = NOAEL (160 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[d] Intermediate-term Dermal MOE = NOAEL (15.8 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[e] Short-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (60 kg).
[f] Intermediate and Long-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).
[g] Short-term Inhalation MOE = NOAEL (5 mg/kg/day)/ Short-term Daily Inhalation Dose (mg/kg/day).
[h] Intermediate-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/ Intermediate-term Daily Inhalation Dose (mg/kg/day).
[I] Total Dose (mg/kg/day) =Short-term Daily Dermal Dose (mg/kg/day) + Short-term Daily Inhalation Dose (mg/kg/day)
[J] BaselineLADD (mg/kg/day) = Total Daily Dose (mg/kg/day) * 15 /365 days per year) * 35 years worked/70 year lifetime.
[k] Baseline Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).

(4) Incident Data

The Agency has reviewed reported poisoning incidents associated with human exposure to imazalil. One pesticide incident occurred in 1997 according to the Incident Data System, which resulted in minor symptoms. No cases of exposure were reported to Poison Control Centers for the time period 1993 through 1996. Detailed descriptions of 24 cases submitted to the California Pesticide Illness Surveillance Program (1982-1998) were reviewed. In 3 of these cases, imazalil was used alone or was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. In the first case, a lemon grader/sorter experienced a rash on her neck, face, and eyelids, which also itched. In the second case, a lemon grader/sorter, who was wearing gloves, wiped her face and experienced a rash. The physician was uncertain as to whether the patient had reacted to the chemical or a possible ringworm infection. In the third case, a worker was repairing a washer-waxer hose line when the product spilled onto his hands. He washed his hands for 15 minutes and experienced a rash on his hands the next day. On the list of the top 200 chemicals for which the National Pesticide Telecommunications Network (NPTN) received calls from 1984-1991 inclusively, imazalil was not reported to be involved in human incidents.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated April 18, 2001, available in the public docket OPP-34253. To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, the species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

Imazalil is registered as a fungicide for seed treatment of small grains (wheat and barley) and for post-harvest waxing of citrus. It can also be used as a disinfectant to sterilize chicken processing facilities by spraying or fumigation. The post-harvest waxing of citrus and the use as a disinfectant to sterilize chicken hatcheries are indoor uses with no potential for significant exposure to fish and wildlife. For seed treatment, application rate is 0.01 lb a.i. per acre (a maximum rate), and only one application is allowed at planting time with one inch soil incorporation. As the result of soil incorporation (i.e., planting of treated /seeds), only 1 % of pesticide applied is expected to remain on the soil surface. Hence, exposure to fish and wildlife from seed treatment is also limited. The Agency believes that, based on the current use pattern of imazalil, the immobile and relatively persistent parent compound is not likely to have adverse effects on the environment.

1. Environmental Fate and Transport

Imazalil has the following characteristics:

- moderate water solubility (water solubility = 180 ppm)
- very stable to hydrolysis at pH 5, 7, and 9
- photodegrades relatively rapidly with a half-life of 36 hours in water
- degrades very slowly in soil under aerobic conditions (half-life 166 days)
- immobile in soils (K_d range from 29-195 mL/g with an average of 130; K_{oc} ranged from 2,081-6,918 mL/g with an average of 4,324 mL/g).
- not expected to volatilize (vapor pressure=$1.2x10^{-6}$ mmHg; Henry's Law constant=$2.6x10^{-9}$ atm m^3/mol).
- high octanol water partition coefficient (K_{ow}=6,607).

a. Degradation and Mobility

Imazalil does not hydrolyze at pH 5, 7, and 9. It photodegrades rapidly in the neutral aqueous environment (with a half-life of 36 hours). The photolytic fate of imazalil on the soil surface is unknown. By aerobic microbial metabolism, imazalil degraded relatively slowly in a loam soil with a half-life of 166 days. Characterization of residues resulted in isolation of fraction FX which reached a maximum level (7% of the applied) at 70 days after application. This fraction was found to consist of two components. Component I is 1-[2-(2,4-dichlorophenyl)-2-hydroxyethyl-1H-imidazole. The structure of component II was not confirmed. By the end of the study period (one year), 22% of the radioactivity had been mineralized to CO_2. About 32% of the radioactivity was found to be soil-bound.

Based on the organic carbon adsorption coefficients (K_{oc}) obtained from the adsorption studies, imazalil is classified as a chemical with a "low" soil mobility potential (average K_{oc} from 8 soils=4,324 mL/g; average K_d from 8 soils=130 mL/g; Van Leemput, et. al.; 1986; Accession number 00148072). The potential for the parent compound to move into ground water and to move with surface runoff water is very low.

The mobility of ^{14}C-labeled (at 2-ethyl carbon) imazalil was also evaluated in a soil column leaching study. Imazalil was found to be immobile in loam and sandy soils. The majority of imazalil remained in the top soil zone (95.7% of the applied was detected in the 0-2.5 cm zone for the loam soil column whereas 84.5% was detected in the same zone for the sand soil column). No residues were detected in the leachates. In sum, imazalil degrades slowly in soil and is not mobile.

b. Bioconcentration

No study was conducted to evaluate the accumulation of imazalil in fish. Based on its high octanol water partition coefficient (K_{ow}=6,607), imazalil is expected to accumulate in fish. However, the use of imazalil as a seed treatment for wheat and barley, along with its fate properties, mitigates the likelihood that this chemical will reach surface water and accumulate in fish.

c. Water Resource Assessment

Imazalil is unlikely to contaminate surface and ground waters. Fate studies show that this chemical is immobile (average Koc = 4,324 mL/g; average Kd = 130 mL/g) and is not expected to move offsite when used as a seed treatment. Both surface and ground water simulations (described below) show that imazalil may reach drinking water supplies only at very low concentrations. The Agency does not have access to any water monitoring data for imazalil.

(1) Surface Water

Indoor uses are not evaluated for their potential to contaminate surface waters because contamination from normal use is considered unlikely. Modeling for imazalil is based on its application as a seed treatment. For the aquatic ecological risk assessment, Estimated Environmental Concentration (EEC) values based on the GENEEC model are used. The Tier 1 model calculates EECs of a pesticide transported from a 10 hectare field to a 1hectare, 2 meter deep pond in a high rainfall scenario using basic environmental fate properties listed in the table below. The resulting LOCs are not exceeded when modeling with these very conservative assumptions. The Agency has higher tier models which, if run, would provide much lower estimated concentrations. Also, GENEEC predicts that 10% of the pesticide applied to a 10 acre field will reach a one-acre pond via run-off. In the actual field conditions, Agency scientists believe less than one percent of the amount applied will reach surface water because of the limited water runoff in the arid wheat growing environment.

Input parameters for GENEEC (Table 7) were selected according to current EPA guidance. The peak concentration predicted by GENEEC is 0.072 ppb, while the 56-day average value is 0.037 ppb.

Table 7: GENEEC Input Parameters.

Parameter	Value
Application number per year	1
Application Rate	0.01 lb ai/acre
Aerobic Soil Metabolism Half Life	166 days
Aerobic Aquatic Half Life	n/a
Organic Carbon Partitioning Coefficient (K_{oc})	2,081 mL/g (minimum)

(2) Ground Water

Ground water concentrations from the seed treatments were predicted with SCI-GROW. The Agency's Tier 1 groundwater screening model. Input parameters were chosen according to EPA's current guidelines and are summarized in Table 8. The predicted groundwater concentration is negligible (0.0002 ppb).

Table 8: SCI-GROW input parameters for imazalil.

Parameter	Value
Application number per year	1
Application Rate	0.01 lb ai/acre
Aerobic Soil Half Life	166 days
Organic Carbon Partitioning Coefficient (K_{oc})	4,026 mL/g (median Value)

2. Ecological Toxicity

The acute and chronic toxicity data for terrestrial organisms exposed to imazalil are summarized in Table 9 below. The Agency evaluates risks to non-target organisms using the "risk quotient" (RQ) method of comparing the ratio of the expected environmental concentrations (EECs) and the toxicity endpoints (such as an LD_{50}) with a set level of concern (LOC). Results of imazalil ecological risk assessments show that none of the RQ values exceed the LOCs for either terrestrial or aquatic non-target organisms. Minimal risk to these organisms is expected (see Tables 10 and 11). There are no fish or wildlife incident reports found in EPA's Ecological Incident Information System.

The granular approach is used to assess terrestrial ecological risk of residues on treated seeds. In granular pesticides, active ingredients are impregnated/mixed with the inert materials. These active ingredients are expected to be slowly released to inhibit pathogens, while with treated seeds, a coating of active ingredient adheres tightly to the seed surface to protect seeds. Based on terrestrial RQ values, none of the LOCs is exceeded. Minimal risk is expected for terrestrial nontarget organisms.

Table 9: Summary of acute and chronic toxicity data for terrestrial organisms exposed to Imazalil.

Species	Acute Toxicity				Chronic Toxicity	
	LD_{50} (mg/kg)	Acute Oral Toxicity (MRID)	5-day LC_{50} (ppm)	Subacute Dietary Toxicity (MRID)	NOAEC/LOEC (ppm) (MRID)	Affected Endpoints (MRID)
Ring-necked Pheasant *Phasianus colchicus*	2000	slightly toxic (163243)				
Northern bobwhite quail *Colinus virginianus*			> 5,620	practically nontoxic (30543)	250 /500 (41663801)	Body weight
Mallard duck *Anas platyrhynchos*	--	--	6290	practically nontoxic (30542)	250 /500 (42039801)	Embryo viability/ hatchability
Laboratory rat *Rattus norvegicus*	343	Moderately toxic (00031596)	--	--	300/1200 (42570701)	Body weight reproduction

a. Risk to Birds

Based on the available data, imazalil is practically nontoxic to slightly toxic to birds from acute exposure. A chronic toxicity study with mallard ducks indicated effects on embryo viability and hatchability, while body weight loss was observed with bobwhite quails (NOAEC = 250 ppm). On the basis of risk quotients, imazalil use at the recommended application rates will not result in an acute or chronic risk to avian species. In fact, the Agency determined that a non-target organism would have to eat a large quantity of treated seeds before receiving a lethal dose based on the low exposure and low toxicity to organisms. No LOCs were exceeded due to the low application rate and minimal exposure (See Table 10). Although imazalil has a potential to interfere with calcium metabolism in birds, no evidence of eggshell thinning was observed in the submitted avian chronic study.

Table 10: Acute and chronic risk quotients for avian species following exposure to imazalil applied at the proposed maximum application rates for wheat and barley.

Crop Application Rate # of apps/interval	Bird type and Body weight (g)	% of Pesticide Left on the Surface	Acute Risk Quotient			Chronic Risk Quotients
			Exposed mg/ft2	Adjusted LD50 (mg/kg)	Acute RQ(LD50/ft2)	Birds NOEC = 250 ppm
Wheat 0.01 lbs. a.i./A 1/season	Song bird (20)	1	0.001	40	0.00003	0.4
	Upland Gamebird (180)	1	0.001	360	0.000003	
	Waterfowl (1000)	1	0.001	2000	0.000001	
Barley 0.01 lbs. a.i./A 1/season	Song bird (20)	1	0.001	40	0.00003	
	Upland Gamebird (180)	1	0.001	360	0.000003	
	Waterfowl (1000)	1	0.001	2000	0.000001	

b. Risk to Mammals

Imazalil is moderately toxic to rats following acute exposure. In the two generation rat chronic study, effects on body weight and litter size were observed (NOAEC = 300 ppm). On the basis of risk quotients, imazalil use at the recommended application rates will not result in an acute or chronic risk to mammal species. No LOCs were exceeded due to the low application rate and minimal exposure.

Table 11: Acute and chronic risk quotients for mammals following exposure to imazalil applied at the proposed maximum application rates for wheat and barley.

Crop Application Rate # of apps/interval	Body weight (g)	% of Pesticide Left on the Surface	Acute Risk Quotient			Chronic Risk Quotients
			Exposed mg/ft2	Adjusted LD50 (mg/kg)	Acute RQ(LD50/ft2)	Mammals NOEC = 300 ppm
Wheat 0.01 lbs. a.i./A 1/season	15	1	0.001	5.145	0.0002	0.3
	35	1	0.001	12.005	0.0008	
	1000	1	0.001	343	0.000003	
Barley 0.01 lbs. a.i./A 1/season	15	1	0.001	5.145	0.0002	
	35	1	0.001	12.005	0.0008	
	1000	1	0.001	343	0.000003	

c. Risk to Aquatic Species

Imazalil is moderately toxic to both freshwater fish and invertebrates in terms of acute toxicity (LC_{50} range of 1.48-3.99 ppm for fish and EC_{50} for daphnids - see Table 12). On the basis of risk quotients, imazalil did not exceed any of the Agency's levels of concern for freshwater organisms. Because of the extremely low exposure to freshwater organisms, acute toxicity testing for estuarine aquatic organisms and all chronic testing have been waived.

Table 12: Summary of acute toxicities for freshwater organisms exposed to imazalil.

Species	96-hr LC_{50} (ppm)	48-hr EC_{50} (ppm)	Acute Toxicity (MRID)
Rainbow trout *Oncorhychus mykiss*	1.48	--	moderately toxic (41606102)
Bluegill sunfish *Lepomis macrochirus*	3.99	--	moderately toxic (41606101)
Waterflea *Daphnia magna*	--	3.54	moderately toxic (41606103)

Table 13: Acute EECs and risk quotients for freshwater fish and invertebrates exposed to imazalil.

Crop Application Rate # of apps / interval	EECs	RQs	
	Peak (ppm)	Freshwater Fish LC_{50} = 1.48 ppm	Freshwater Invertebrate LC_{50} = 3.54 ppm
Wheat/barley 0.01 lbs. a.i./A, One application at planting	0.00007	0.00005	0.00002

d. Endangered Species

The LOCs for risks to endangered species are not exceeded for the use of imazalil as a seed treatment. The other currently registered uses of imazalil will not have an effect on endangered species because they are indoor uses and there is no environmental release. Therefore, imazalil will have no effect on federally listed endangered and threatened species from the uses discussed in this RED.

IV. Risk Management, Reregistration and Tolerance Reassessment

A. Determination of Interim Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing imazalil as an active ingredient.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of imazalil. The dietary and aggregate risk assessments and resulting tolerance reassessment can be found in the Tolerance Reassessment Decision (TRED) document dated July 12, 2002 (attached as Appendix C to this document). You may also view this document at EPA's electronic public docket system, http://www.epa.gov/edocket/. Once in the system, select "search," then key in the appropriate docket ID number, OPP-2002-0333. In the July 12, 2002 TRED document, EPA determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to imazalil when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, the tolerances established for residues of imazalil in/on raw agricultural commodities were reassessed and considered reassessed as safe under section 408(q) of the FFDCA.

Based on a review of these data and public comments on the Agency's assessments for the active ingredient imazalil, EPA has sufficient information on the human health and ecological effects of imazalil to make a reregistration eligibility decision under FIFRA. The Agency has determined that imazalil products are eligible for reregistration provided that: (i) any

current data gaps and additional data needs are addressed; and (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

Label changes are described in Section V. Appendix A lists the uses deemed eligible for reregistration by the Agency. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of imazalil, and lists the submitted studies that the Agency found acceptable.

B. Public Comments and Responses

When making the reregistration decision, the Agency took into account all comments received after opening of the public docket. These comments in their entirety are available in the imazalil docket (OPP#2003) in the OPP Public Regulatory Docket. Comments on the risk assessment were submitted by the registrants, and grower groups. Comments were submitted in the following area:

- Worker protection: Many commenters raised concerns with the use of chemical resistant gloves in citrus packing houses. (Extreme heat, allergic reactions, and cosmetic damage to citrus). Many commenters also questioned the Agency's assumption for dermal absorption rates in light of the use of imazalil in wax formulations.

- Worker Exposure: Several commenters noted that exposure during drenching operations are extremely low due to remote operations and mechanization of the process.

- Cancer Assessment: Many commenters urged the Agency to defer any decision regarding the appropriate cancer model for imazalil until all cancer studies have been submitted and reviewed.

- Use in Chicken Hatcheries is not a Food Use: A commenter wanted to clarify that imazalil is not used in chicken hatcheries when eggs or poultry are present, and therefore, the Egg and Poultry Fumigation Study required in the TRED is not needed.

Regarding the use of chemical resistant gloves, the Agency reviewed the assumptions used in its initial assessment of post-application occupational risk from exposure to imazalil treated citrus and has concluded that the assumptions regarding dermal contact and dermal absorption were very conservative, and therefore the risks for this scenario are below the Agency's level of concern. The Agency is also requiring confirmatory data to ensure that no undue risks exist. On the drenching issue, the Agency agrees that exposure to imazalil is limited due to remote operation of drenching equipment. Finally, the Agency believes sufficient cancer data exist to support issuance of the RED at this time. The Agency will review additional information regarding the cancer assessment and will reconsider the appropriateness of the linear low dose model depending on the results of that review. Regarding the use of imazalil in chicken hatcheries, EPA agrees that the labels for imazalil products registered for use in chicken hatcheries state that imazalil is for use on poultry equipment prior to the introduction of eggs. Therefore, EPA will not require the Egg and Poultry fumigation study as discussed in the July

12, 2002, TRED.

C. Regulatory Rationale

1. Occupational Risk Mitigation

a. Handler Risk Mitigation

The Agency has determined that there are potential exposures to mixers, loaders, applicators, or other handlers resulting from application of imazalil for seed treatment, citrus, and chicken hatcheries. All handler scenarios are acceptable in the short and intermediate-term with baseline attire, except mixing/loading liquid formulation for waxing equipment (scenario 3 on Table 4). However, in order to address cancer risks, EPA has determined several scenarios will need chemical resistant gloves (including scenario 3). The scenarios where chemical resistant gloves are needed to address cancer risks in addition to baseline protection are listed below. In most cases, the current label already requires all handlers to wear chemical resistant gloves.

Handler Scenarios Needing Chemical Resistant Gloves in Addition to Baseline Attire:

- Mixing/Loading Liquid for on-farm seed treatment (Scenario 1).
- Mixing/Loading liquid for drencher application (Scenario 2).
- Mixing/Loading liquid for waxing equipment (Scenario 3).
- Mixing/Loading liquid for foaming equipment (Scenario 4).
- Handling for commercial seed treatment (Scenario 10).
- Mixing/Loading and applying liquid with commercial seed treatment equipment (Scenario 12).
- Mixing/Loading/applying seed treatment for on-farm seed treatment (Scenario 13).

No additional risk mitigation beyond chemical resistant gloves is being required for mixing/loading/applying imazalil for on-farm seed treatment (Scenario 13). Although the cancer risks calculated by the Agency are between 1.5×10^{-4} and 2.25×10^{-4}, these risk numbers are based on a screening level conservative risk assessment. As noted in Section III.A.2.c.2., the calculations used to derive these cancer risk numbers are based on a published study where a dust formulation was used to derive dermal exposure estimates. Dust formulations, which can linger in the air, have a significantly higher potential for exposure than the imazalil emulsifiable concentrates formulation actually used for on-farm seed treatment. Therefore, the Agency concludes that the actual risk to mixer/loader/applicators for on-farm seed treatment with imazalil are acceptable as long as chemical resistant gloves are used.

As stated in Section III, there were insufficient data for the Agency to quantify risks for the following 5 scenarios.

- Mix/load of liquid with foaming equipment (scenario 4)
- Application of liquid with drencher (scenario 6)
- Application of liquid with foaming equipment (scenario 7)
- Application of liquid with waxing equipment (scenario 8)
- Application lighting and using smoke canister for chicken hatchery (scenario 11)

The Agency does not expect the risks from mixing and loading imazalil for use in foaming equipment (scenario 4) to be very different from mixing and loading imazalil liquid for use in waxing equipment (scenario 3), which does not exceed the Agency's level of concern with the use of chemical resistant gloves. Additionally, Jenssen Pharmaceutica, one of the registrants of the liquid formulations of imazalil that can be used to treat post-harvest citrus, has indicated in their comments to the revised imazalil risk assessment that they intend to voluntarily cancel the use of imazalil for foaming equipment. There are two other registrants that continue to support this use. However, based on comments from the citrus industry, foaming is not commonly used and they support the voluntary cancellation of this application method.

EPA was not able to conduct a quantitative risk assessment for application of imazalil liquid formulations for waxing and foaming equipment and truck-bed drenchers (scenarios 6, 7 and 8). However, since the completion of the risk assessment, EPA concluded that occupational exposure for these scenarios is not likely because these operations are performed by remote control and there are no workers present. In the case of drenchers, in order to assure that no workers are present, EPA believes a label statement must be added which requires workers to leave the treatment area until the citrus has been drained. There must also be a label statement requiring the windows and doors of the truck to be closed prior to treatment. EPA believes these label requirements are consistent with current industry practice; however, EPA would like to ensure these practices are followed. EPA does not believe any further label statements are needed to ensure that workers are not exposed during application of imazalil liquid for use with waxing equipment for citrus packing.

As noted in Section III.A.c.1., the Agency did a very conservative risk assessment for handler risk from smoke generators containing imazalil. EPA believes that as long as all workers immediately leave the treatment site after lighting the smoke canisters, the occupational risks for this scenario are significantly lower than what was calculated in the screening level assessment. The Agency does not expect this exposure scenario to be of concern. However, to ensure workers are not exposed for this scenarios, smoke canisters containing imazalil for use in chicken hatcheries must have a label statement which requires all workers to immediately leave the treatment area after lighting the smoke canister.

b. Post-application Risk Mitigation

For Citrus Foaming and Waxing

The cancer risk estimates for workers handling citrus after waxing or foaming is 6.68×10^{-4}; however, the Agency considers this exposure estimation to be very conservative. The Agency's risk assessment assumed that 100% of the imazalil on the citrus fruit would be transferred to the skin. However, based on the Brouwer study (1999), the efficiency of transfer is likely to be less than 2%, of the residue on the surface. This is a 50-fold reduction in exposure which reduces the risk 50-fold as well. Also, imazalil is usually part of a wax matrix which EPA believes reduces the potential for substantial transfer to the skin. Finally, the transfer coefficients for the hands were obtained from a field study in which contact with contaminated foliage was highly probable; a conveyor belt treatment line would be unlikely to have such a high degree of contact (probably restricted to fingertips only).

EPA considered requiring chemical resistant gloves to further reduce imazalil exposure to workers handling imazalil treated waxed citrus. Comments from the citrus packing industry during the reregistration public comment period (phase 5 of the reregistration process) indicated that use of chemical resistant gloves (i.e., latex gloves) would be a problem for the industry. Use of latex gloves would smudge the wax on the fruit. This is a cosmetic issue that hurts the marketability of the fruit. The use of latex gloves would also be a heat and comfort burden to workers on the packing line. In light of these concerns, The Agency reviewed the assumptions used in the risk assessment for this exposure scenario and has concluded that the assumptions regarding dermal contact were very conservative. Therefore, based on the conservative nature of the assessment, described above, the Agency believes the risk to workers for this scenario are below the level of concern even without chemical resistant gloves. To confirm this conclusion and refine our risk estimates, the Agency will require data on the availability of imazalil when it is either part of a wax matrix or encapsulated with wax.

Use in Chicken Hatcheries

Given the nature of the activities at egg handling facilities as discussed previously, EPA believes that there is minimal dermal or inhalation exposure to imazalil in chicken hatcheries following imazalil applications, as long as label recommendations are followed. Further, based on the low vapor pressure and short half life (118 minutes) of imazalil, the Agency concludes that the reentry and ventilation recommendations currently on the imazalil labels would adequately mitigate worker's inhalation or dermal exposures and risks following smoke generator and EC applications. However, since current label language makes only recommendations for reentry and ventilation, EPA concludes the current recommendations must become requirements. In the case of smoke generators:

- All workers must be prohibited by the label from reentering the treated area if smoke is still visible.

- Workers must be prohibited from reentering unventilated areas for 12 hours. For

ventilated areas, workers may reenter after two hours provided that at least one air exchange has occurred during that period.

For the EC formulation applied by handheld equipment in chicken hatcheries:

- Workers must be prohibited from reentering unventilated areas for 12 hours. For ventilated areas, workers may reenter after two hours provided that at least one air exchange has occurred during that period.

EPA was not able to assess the risks to workers entering a treatment site for the purposes of disposing the used smoke canister. Because of the possibility of imazalil residues on used smoke canisters, and to ensure that workers are not exposed to imazalil, chemical resistant gloves must be worn when handling used smoke canisters for disposal.

Finally, as stated in the Public Comments and Response section of this RED, imazalil is not registered for use in chicken hatcheries when eggs or poultry are present. For that reason, EPA will not require the Egg and Poultry Fumigation Study listed in the July 12, 2002 , TRED. However, the current label language does not state this clearly as a use direction. Therefore, a statement must be added to the label that says, "This product may not be used when eggs or poultry are present."

Planting Imazalil-Treated Seeds

An estimate of the loading and planting of treated seed was conducted for descriptive purposes using relatively conservative assumptions. While the result of this assessment shows a risk of concern ($1.3x10^{-5}$ to $1.41x10^{-5}$) as shown on Table 6, these results are being used by the Agency for a comparative range of exposure. The exposure was calculated using PHED data for granular formulations, which makes this a very conservative estimate of the actual risk for handling treated seed (see discussion in Section III.A.2.c.(3) under the discussion for Post-Application Occupational Risk From Imazalil Treated Seed). The Agency does not believe this is a post-application risk of concern and no risk mitigation is required for this scenario.

As stated earlier, the Agency did not conduct a quantitative assessment to calculate the post-application risk to workers exposed to imazalil-treated seed which has been planted. The Agency believes that there is a low potential for re-entry exposure for this scenario since the seeds are below the surface of the ground and therefore not available for worker exposure. However, because the acute toxicity for imazalil is category 1 for eye irritation, EPA will maintain the 48 hour REI for at plant seed treatment.

2. Environmental Risks Mitigation

Based on the Agency's risk assessment, none of the RQ values trigger LOC exceedences for either for either terrestrial or aquatic non-target organisms, and minimal risk to the environment is expected. No environmental risk mitigation is necessary.

3. Other Labeling Requirements

Other use and safety information need to be placed on the labeling of all end-use products containing imazalil, in addition to the mitigation measures listed above and other existing label requirements. For the specific labeling statements, refer to Section V of this document.

a. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Agency's review of imazalil resulted in a determination that imazalil will have "no effect" on threatened and endangered species.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. These Pamphlets are available for voluntary use by pesticide applicators, on EPA's web site at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

V. What Registrants Need to Do

In order for imazalil to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in sections IV and V, which include, among other things, submission of the following:

A. Data Call-In (DCI) Responses

For imazalil technical grade active ingredient products, registrants need to submit the following items:

Within 90 days from receipt of the generic data call-in (DCI): (1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and (2) submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI: cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Meghan French at (703) 308-8004 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
Meghan French
US EPA (604w32)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Meghan French
Office of Pesticide Programs (604w32)
Crystal Mall 2, Room 266A
1801 South Bell Street
Arlington, VA 22202

For products containing the active ingredient imazalil, registrants need to submit the following items for each product:

Within 90 days from the receipt of the product-specific data call-in (PDCI): (1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and (2) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI: (1) two copies of the confidential statement of formula (EPA Form 8570-4); (2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration"; (3) five copies of the draft label incorporating all label amendments outlined in Table 14 of this document; (4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); (5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and (6) the product-specific data responding to the PDCI.

Please contact Venus Eagle at (703) 308-8045 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (DCI/PRB)
Venus Eagle
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/PRB)
Venus Eagle
Office of Pesticide Programs (7508C)
Crystal Mall 2, Room 266A
1801 South Bell Street
Arlington, VA 22202

B. Manufacturing Use Products

1. Additional Generic Data Requirement

The generic data base supporting the reregistration of imazalil has been reviewed and determined to be substantially complete. The outstanding or confirmatory data required to complete the generic data base and/or refine the dietary, occupational and ecological risk assessments are listed below. These studies include data requirements listed in the July 12, 2002 TRED.

- OPPTS GLN 870.6300 Developmental Neurotoxicity in Rats
- OPPTS GLN 870.6200 Acute Neurotoxicity Study in Rats
- OPPTS GLN 870.6200 Subchronic Neurotoxicity Study in Rats
- OPPTS GLN 860.1200 Direction for Use
- OPPTS GLN 860.1340 Residue analytical method-Animal Commodities
- OPPTS GLN 850.4400 Tier I aquatic plant growth studies with two species of aquatic plants (*Lema gibba* and *Selenastrum capricornutum*).
- OPPTS GLN 830.7050 UV/Visible Light Absorption
- Special Study: To determine the availability imazalil from treated citrus. Study to determine of availability of imazalil from citrus encapsulated by wax and imazalil as part of a wax matrix.

The July 12, 2002 TRED discussed the need to require OPPTS GLN 860.1480, Egg and Poultry Fumigation study. However, because EPA has determined that there are no registered uses in the United States for which eggs or poultry should be exposed to imazalil, the final DCI will not include this study. Additionally, the registrant has indicated that they already submitted a study to satisfy OPPTS GLN 860.1340, Residue analytical method-Animal Commodities. If this submitted study is satisfactory, it will meet the data requirement listed above.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP should bear the labeling contained in Table 14 , Label Changes Summary Table**,** at the end of this section.

B. End-Use Products

1. Additional Generic Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submission to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each

product. A product-specific data call-in, outlining specific data requirements also accompanies this RED.

2. Labeling for End-Use Products

Label changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes are specified in Table14: Labeling Changes Summary Table, at the end of this section.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Interim Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this interim RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell imazalil products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrants may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than the registrants remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

In order to be eligible for reregistration, all product labels shall be amended to incorporate the risk mitigation measures outlined in Section IV. Table 14 describes how language on the labels should be amended. Label language in Table 14 enclosed in quotation marks represents exact language that should appear on the label. Instructions that are not enclosed in quotation marks represent actions that the registrant must take to amend their labels or product registrations in order for products to be reregistered.

Table 14: Summary of Labeling Changes for Imazalil		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into a *fungicide* for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

Table 14: Summary of Labeling Changes for Imazalil		
Description	**Amended Labeling Language**	**Placement on Label**
PPE Requirements Established by the RED[1]	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All handlers must wear: Long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, *except* for bag sewers, planters, truck drivers, and sorters. Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 14: Summary of Labeling Changes for Imazalil		
Description	**Amended Labeling Language**	**Placement on Label**
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following User Safety Requirements (Must be placed in a box.)
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application."	Directions For Use under General Precautions and Restrictions
Application Restrictions for use in Chicken Hatcheries.	"This product may not be used when eggs or poultry are present."	Directions For Use
Application Restrictions for Smoke Generator Applications to Chicken Hatcheries	"The treatment site must be vacated immediately after lighting the smoke canister."	Directions For Use
Application Restrictions for Citrus Drench	"Stay outside of treatment area until citrus is treated and drained." "The windows and doors of the transport vehicle must be closed prior to treatment"	Directions For Use under General Precautions and Restrictions

Table 14: Summary of Labeling Changes for Imazalil		
Description	**Amended Labeling Language**	**Placement on Label**
Restricted-Entry Interval for products that contain uses within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) – see PR Notice 93-7	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI)."	Directions for Use, Agricultural Use Requirements Box
Reentry Restrictions for Smoke Generator Applications to Chicken Hatcheries	The following text must be added to the label: "Do not reenter the treated area if smoke is still visible." "Do not reenter the unventilated area for at least 12 hours. For ventilated areas, do not reenter treated areas for at least 2 hours, provided that at least 1 air exchange has occurred during that period." "After the ventilation requirements have been met, workers entering the treatment area to remove smoke canisters must wear chemical resistant gloves."	Directions For Use
Reentry Restrictions for Handheld Equipment Applications in Chicken Hatcheries	"Do not reenter the unventilated area for 12 hours. For ventilated areas, do not reenter treated areas for at least 2 hours, provided that at least 1 air exchange has occurred during that period."	Directions For Use
Early Entry Personal Protective Equipment *Required for products that allow seed treatment use at planting.*	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, shoes plus socks, chemical-resistant gloves made of any waterproof material, and protective eyewear."	Directions for Use, Agricultural Use Requirements Box

Table 14: Summary of Labeling Changes for Imazalil		
Description	**Amended Labeling Language**	**Placement on Label**
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
Environmental Hazards for products used in seed treatments only	"Environmental Hazards" "This chemical is toxic to fish. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements under Environmental Hazards
Environmental Hazards for products used for outdoor terrestrial uses	"Environmental Hazards" "This chemical is toxic to fish. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate."	Precautionary Statements under Environmental Hazards
Environmental Hazards *Required for in field seed treatment.*	"Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters. Apply this product only as specified on this label."	Precautionary Statements immediately following the User Safety Recommendations

Table 14: Summary of Labeling Changes for Imazalil		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions for seed that has been treated with this product that is then packaged or bagged for future use	Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling: "This bag contains seed treated with imazalil. When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves." "Treated Seed - Do Not Use for Food, Feed, or Oil Purposes." "After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	Directions for Use

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

IV. APPENDICES

Appendix A. Imazalil Table Use Patterns Eligible For Reregistration

Site Application Timing Application Type Application Equipment	Formulation	Maximum Single Application Rate	Maximum Number of Applications Per Season	Maximum Seasonal Rate	Preharvest Interval, Days	Use Directions and Limitations
Terrestrial Wheat and Barely Barley and Wheat						
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	2% IM	.003984 lb cwt	Not specified (NS)	NS	NS	Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	1.2% FIC	003906 lb ai/cwt	Not specified (NS)	NS		Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.

Site Application Timing Application Type Application Equipment	Formulation	Maximum Single Application Rate	Maximum Number of Applications Per Season	Maximum Seasonal Rate	Preharvest Interval, Days	Use Directions and Limitations
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	31% RTU	.01 lb cwt				
Seed treatment Mechanical slurry of seed treatment equipment	10% EC	.01008 lb ai/cwt	Not specified (NS)	NS	NS	Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	9.5% (0.84 lb/gal) EC 9.5% RTU	1.5 fl. oz of product/100 lbs of seed(cwt) or 0.01 lb ai/cwt (equivalent to 100 ppm; mg ai/kg seed) .009844 lb cwt	Not specified (NS)	NS	NS	Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.
Seed treatment Mechanical slurry or mist-type of seed treatment equipment	44.5% EC	0.34 fl. oz of product/100 lbs of seed(cwt) .01116 lb cwt	Not specified (NS)	NS	NS	Treated seeds should be adequately dyed, and any dye added to treated seeds must be cleared for use under 40 CFR §180.1001. Treated seeds should not be used for food, feed, or oil purposes. The grazing or feeding of livestock on treated areas for six weeks after planting is prohibited.
Citrus Fruits						

Site Application Timing Application Type Application Equipment	Formulation	Maximum Single Application Rate	Maximum Number of Applications Per Season	Maximum Seasonal Rate	Preharvest Interval, Days	Use Directions and Limitations
Post-harvest treatment Dips, wash tanks, and drenches	44.6% (4.17 lb/gal) EC 44.5% EC and	19.2 fl. oz of product/100 gal water or 750 ppm ai	2	4000ppm ai	Not applicable (NA)	Application should be made in dips, wash tanks, and drenchers. Length of dip time should not exceed 2 minutes.
Post-harvest treatment Wax		25.5 fl. oz of product/100 gal water or 1000 ppm ai	2 (Should not exceed 4000 ppm total) *or* 1 application of 4000ppm in wax	4000ppm ai	NA	Application should be made to freshly cleaned fruits immediately prior to waxing.
Post- harvest treatment Spray brush		25.5 fl. oz of product/100 gal water or 1000 ppm ai	2	4000ppm ai	NA	Application should be made after washing and prior to wax application.
Post-harvest treatment Foamer		51.0 fl. oz of product/100 gal water or 2000 ppm ai	2	4000ppm ai	NA	Application should be made as a ready-to-use foam detergent using a mechanical foamer.
Post-harvest treatment Dips, wash tanks, and drenches	22.2% EC	Dilute 1 part product with 110 water or 2000 ppm ai	2 (Should not exceed 4000 ppm total) *or* 1 application of 4000ppm in wax	4000 ppm ai	NA	Same as above

Site Application Timing Application Type Application Equipment	Formulation	Maximum Single Application Rate	Maximum Number of Applications Per Season	Maximum Seasonal Rate	Preharvest Interval, Days	Use Directions and Limitations
Chicken Hatcheries						
Smoke Generator Treatment/Disinfection of Equipment prior to introduction of eggs.	13.80% FC 14.9% IMPR	3.171x10-04 lb 1K cu.ft .02756 lb 1K cu.ft.	Not specified (NS)	Not specified (NS)	NA	Delay reentry into treatments areas until the smoke has settled or dissipated. Do not reenter unventilated areas for 12 hours after treatment. For ventilated areas, do not reenter area until ventilated ducts and fans have been opened and on for at least 30 minutes and at least 1-2 air exchanges have occurred. For either unventilated or ventilated areas, don not reenter if treatment smoke is still visible.

[1] A 0-day PHI has been established for Costa Rica, Guatemala, Honduras, and Mexico; however, pre-harvest foliar application of imazalil is not registered for use on bananas at this time.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Imazalil

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the chemical case covered by this RED. It contains generic data requirements that apply in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Columns 1, 2 & 3). The data requirements are listed in the order of New Guideline Number and appear in 40 CFR §158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002, (703) 487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial nonfood
   D. Aquatic food
   E. Aquatic nonfood outdoor
   F. Aquatic nonfood industrial
   G. Aquatic nonfood residential
   H. Greenhouse food
   I. Greenhouse nonfood
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor nonfood
   N. Indoor medical

O. Indoor residential

3. Bibliographical Citation (Column 5). If the Agency has acceptable data in its files, this column lists the identification number of each study. Normally, this is the Master Record Identification (MRID) Number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography (Appendix D) for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Imazalil

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
PRODUCT USE CHEMISTRY				
830.1550	61-1	Product Identity and Composition	**All**	40478201, 43016801, 4410702
830.1600	61-2A	Starting Materials and Manufacturing Process	**All**	40478201, 41595901, 41545101, 42403101, 44107202
830.1620	61-2B	Description of Production Process	**All**	40478201, 43223001, 4410702
830.1670	61-2B	Discussion of Formation of Impurities	**All**	40478201, 43223001, 4410702
830.1700	62-1	Preliminary Analysis	**All**	41889801, 44107203
830.1750	62-2	Certification of Limits	**All**	41889801, 42793800, 44107203
830.1800	62-3	Enforcement Analytical Method	**All**	42793801, 44107203
830.6302	63-2	Color	**A**	41889801 41606106 44107204
830.6303	63-3	Physical State	**A**	41606106, 44107205
830.6304	63-4	Odor	**A**	41606106, 44107206
830.7050	None	UV/Visible Absorption	**A**	44107207
830.7200	63-5	Melting Point/Melting Range	**A**	41606106
830.7300	63-7	Density, Relative Density, Bulk Density	**All**	41606106, 44107208
830.7840 830.7860	63-8	Solubility	**All**	42793802, 41606106, 44145401
830.7950	63-9	Vapor Pressure	**All**	41606106,44107218
830.7370	63-10	Dissociation Constant in Water	**All**	41606106, 44107210
830.7550	63-11	Octanol/Water Partition Coefficient	**All**	41606106, 44107211
830.7000	63-12	pH of Water Solutions or Suspensions	**All**	41606106
830.6313	63-13	Stability	**All**	42793802, 41606106, 44134402
830.6316	63-16	Explodability	**All**	41606106
830.6317	63-17	Storage Stability	**All**	41606106
830.6320	63-20	Corrosion Characteristics	**All**	42012001
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity, Bobwhite Quail	**A**	00163243
850.2200	71-2A	Avian Subacute Dietary Toxicity, Bobwhite Quail	**A**	0030542, 0030543
850.2200	71-2B	Avian Subacute Dietary Toxicity, Mallard Duck	**A**	0030542
850.2300	71-4A	Avian Reproduction, Bobwhite Quail	**A**	41663801, 42039801
850.2300	71-4B	Avian Reproduction, Mallard Duck	**A**	41663801, 42039801

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
850.1075	72-1A	Fish Toxicity, Bluegill Sunfish	**A**	41606101, 41606102
850.1075	72-1C	Fish Toxicity, Rainbow Trout	**A**	41606101, 41606102
850.1010	72-2A	Invertebrate Toxicity	**A**	41606103
850.4400	123-2A	Aquatic Plant Growth, Tier 1		Data Gap
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity, Rat	**A**	00031596, 4107272
870.1200	81-2	Acute Dermal Toxicity, Rabbit/Rat	**A**	41606104, 44107213
870.1300	81-3	Acute Inhalation Toxicity, Rat	**A**	41889802, 44107214
870.2400	81-4	Primary Eye Irritation, Rabbit	**A**	41606105
870.2500	81-5	Primary Skin Irritation	**A**	41328801, 44107216
870.2600	81-6	Dermal Sensitization	**A**	41718701, 40271701
870.6200	81-8	Acute Neurotoxicity Screening Battery		Data Gap
870.3100	82-1A	90-Day Subchronic Feeding, Rodent	**A**	43965704
870.3150	82-1B	90-Day Subchronic Feeding, Nonrodent (Dog)	**A**	41328802
870.3200	82-2	21-Day Dermal, Rabbit/Rat	**A**	43016802, 42085201
870.6200	82-7	Subchronic Neurotoxicity Study, Rat		Data Gap
870.4100	83-1A	Chronic Feeding Toxicity, Rodent	**A**	41558501
870.4100	83-1B	Chronic Feeding Toxicity, Norodent (Dog)	**A**	41328802
870.4200	83-2A	Chronic Carcinogenicity (Feeding), Rat	**A**	41558501
870.4200	83-2B	Chronic Carcinogenicity (Feeding), Mouse	**A**	43965703, 42972001, 4293601
870.3700	83-3A	Prenatal Developmental Toxicity, Rat	**A**	44858001, 44567802, 44951001, 41026603
870.3700	83-3B	Prenatal Developmental Toxicity, Rabbit	**A**	43154201, 42593601
870.3800	83-4	2-Generation Reproduction and Fertility Effects, Rat	**A**	42949402, 42570701
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity Study, Rat	**A**	42570701, 47026101
870.6300	83-6	Developmental Neurotoxicity Study, Rat		Data Gap
870.5140	84-2A	Gene Mutation (Ames Test)	**A**	43735003, 40729301
870.5375	84-2B	Structural Chromosomal Aberration	**A**	40729301, 40729302
870.5395	84-2	In vitro Mammalian Cytogenetics Test (Erythrocyte Mirconucleus Assay).	**A**	40729303, 00031599
870.5100	84-2	Bacterial Reverse Gene Mutation Assay Test	**A**	40729301, 40729302,

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation(s)
870.5300	84-2	Detection of Gene Mutations in Somatic Cells in Culture, Mammalian	**A**	4378021
870.5385	84-2	Bone Marrow Chromosomal Analysis, Mammalian	**A**	40729303
870.5575	84-2	Mitotic Gene Conversion in *Saccharomyces Cerevisiae*	**A**	00031599, 43735003, 43965702
870.5500	84-4	Other Genotoxic Effects	**A**	40729303, 43965702, 43780201
870.7485	85-1	General Metabolism, Rat	**A**	43016803, 42012003
870.7600	85-2	Dermal Absorption (Penetration), Rat	**A**	42913401
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	**A**	44833501, In Review
875.2200	132-1B	Soil Residue Dissipation		
875.2400	133-3	Dermal Passive Dosimetry Exposure	**A**	42603401, 44833501, In Review
ENVIRONMENTAL FATE				
None	160-5	Chemical Identity	**A**	41606106
835.2120	161-1	Hydrolysis	**A**	115272, 00248517
835.2240	161-2	Photodegradation, Water	**A**	40926701
835.4100	162-1	Aerobic Soil Metabolism Study	**A**	00158160
835.1240	163-1	Leaching/Adsorption/Desorption	**A**	00148072, 00158160
RESIDUE CHEMISTRY				
860.1100	171-2	Chemical Identity	**A**	40478201
860.1200	171-3	Directions for Use		Data Gap
860.1300	171-4A	Nature of the Residue, Plants	**A**	43965701, 43308401, 4262901 and 42012008
860.1300	171-4B	Nature of the Residue, Livestock	**A**	43076101
860.1340	171-4C	Residue Analytical Method, Plants	**A**	42454803
860.1340	171-4D	Residue Analytical Method, Animals		Data Gap
860.1380	171-4E	Storage Stability	**A**	42626903, 42755301
860.1480	171-4J	Magnitude of Residues in Meat, Milk, Poultry and Eggs	**A**	44786501
Processed Food/Feed Group				
860.1520	171-4L	Processed Food (Barley, Oats and Wheat)	**A**	42868101
860.1520	171-4L	Processed Food (Wheat)	**A**	43285001
Special Study		To determine the availability imazalil from treated citrus. Study to determine availability from citrus encapsulated by wax and imazalil as part of a wax matrix.	**A**	Data Gap

APPENDIX C: Imazalil - Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2,1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of August 23rd, 2003. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on October 22nd, 2003.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at one of the following sites:

http://www.epa.gov/pesticides/reregistration/

http://www.epa.gov/edocket/

APPENDIX D: Imazalil - Citations Considered to be Part of the Database Supporting the Imazalil Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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Appendix E. GENERIC DATA CALL-IN

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. PRODUCT SPECIFIC DATA CALL-IN

See attached table for a list of product-specific data requirements. Note that a complete Product Data Call-In (PDCI), with all pertinent instructions, is being sent to registrants under separate cover.

APPENDIX G. EPA'S Batching of Imazalil Product for Meeting Acute Toxicity Data Requirements for Reregistration.

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing imazalil as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to

Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirteen products were found which contain **Imazalil** as the active ingredient. These products have been placed into one batch and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria for product specific requirements.

Batch 1	EPA Reg. No.	% Active Ingredient
	11678-55	98.50
	43813-02	98.94

No Batch	EPA Reg. No.	% Active Ingredient
	400-438	Imazalil: 2.0 Carboxin: 27.8 Thiabendazole: 2.5
	773-55	13.8
	773-56	14.9
	2792-51	22.2
	2935-440	10.0

No Batch	EPA Reg. No.	% Active Ingredient
	7501-127	31.0
	7501-166	Imazalil: 1.2 Carboxin: 16.7 Thiabendazole: 1.5
	7501-182	Imazalil: 0.43 Metalaxyl: 0.58 Tebuconazole: 0.43
	43813-06	44.6
	43813-14	9.5
	66222-20	44.5

Appendix I. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

   a. Registration Division Personnel Contact List
   B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   C. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)

5285 Port Royal Road

Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.